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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/552,944	08/09/2006	Dusan Miljkovic	100700.0025US1	2489
24992 - 7590 - 04/16/2010 FISH & ASSOCIATES, PC ROBERT D. FISH			EXAMINER	
			MEHTA, HONG T	
2603 Main Str Suite 1000	eet		ART UNIT	PAPER NUMBER
Irvine, CA 92614-6232			1784	
			NOTIFICATION DATE	DELIVERY MODE
			04/16/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

rfish@fishiplaw.com patents@fishiplaw.com

Application No. Applicant(s) 10/552,944 MILJKOVIC ET AL. Office Action Summary Examiner Art Unit HONG MEHTA 1784 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on January 15, 2010. 2a) ☐ This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 1-3 and 5-20 is/are pending in the application. 4a) Of the above claim(s) _____ is/are withdrawn from consideration. 5) Claim(s) _____ is/are allowed. 6) Claim(s) 1-3 and 5-20 is/are rejected. 7) Claim(s) _____ is/are objected to. 8) Claim(s) _____ are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are; a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abevance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received.

1) Notice of References Cited (PTO-892)

Paper No(s)/Mail Date

Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO/SB/08)

Attachment(s)

Interview Summary (PTO-413)
 Paper No(s)/Mail Date.

6) Other:

5) Notice of Informal Patent Application

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DETAILED ACTION

This office action is in response to applicant's remarks filed on January 15, 2010.

Pending amended claims 1-3 and 5-20 are under examination. Claim 4 is cancelled.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

- 2. Claims 1, 10 and 18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.
- 3. The term "polyphenol-enriched" in claim 1, line 8; term "nutrient-enriched extract" in claim 10, lines 7-8 and term "polyphenol-rich extract" in claim 18, line 3-4 are not supported by instant specification. These terms have no clear support within the instant specification for "polyphenol-enriched", "nutrient-enriched extract" and "polyphenol-rich extract" hence they are new matter. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

 Claim 1, 10 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Art Unit: 1784

5. The terms "enriched" and "rich" are indefinite and vague because it is not clear if a substance is added to the composition or is the composition is inherently present in a particular substance. Examiner considers the terms "enriched" and "rich" as inherent properties of coffee cherries in relation to a ripeness stage from semi-ripe, almost ripe and unripe and with or without defects/blemishes which is consistent with the instant specification page 8. lines 12-24 and pages 17-20.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filled in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filled in the United States before the invention by the applicant for patent, except that an international application filled under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filled in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
- Claims 1, 6-10, and 12-14 are rejected under 35 U.S.C. 102(e) as being anticipated by Miljkovic et al. (2002/0187239A1).

The applied reference has a common inventor with the instant application.

Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

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8. Regarding claims 1, 7, 8, 9 and10, Miljkovic et al. discloses a method of extracting ground (comminuted) whole coffee cherries which includes the husks, skins and seeds (page 4, [0030]; page 6, Example 1-5) with water as solvent to obtain an enriched dry extract with polyphenols such as caffeic acid, ferulic acid and chlorogenic acid to dry or liquid state (pg. 4, [0031], [0033], [0034], [0036] and pg. 6, [0049]) and recombined with beverages such as tea (pg. 6, [0057], Table 1) and food suitable for human consumption (pg. 4, [0032], pg. 6, [0051]).

- Regarding claim 6, Miljkovic et al. discloses liquid extract from coffee cherry extraction is vacuum evaporated (pg. 6, [0049]).
- Regarding claim 12, 13 and 14, Miljkovic et al. discloses high pressure liquid chromatography to produce factions of polyphenols including caffeic acid, ferulic acid and chlorogenic acid (og. 6, 100491) considered as nutrients.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

- 12. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
 - 1. Determining the scope and contents of the prior art.
 - 2. Ascertaining the differences between the prior art and the claims at issue.
 - 3. Resolving the level of ordinary skill in the pertinent art.

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 Considering objective evidence present in the application indicating obviousness or nonobviousness.

- 13. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).
- 14. Claims 2, 3, 5, 11, 15-19 and 20 rejected under 35 U.S.C. 103(a) as being unpatentable over Miljkovic et al. (2002/0187239A1) as applied to claim 1 and 10 above, and further in view of Bucheli et al. (J. Agric. Food Chem. 48, 1358-1362).
- 15. Miljkovic et al. discloses a method of extracting ground (comminuted) whole coffee cherry which includes the husks, skins and seeds (page 4, [0030]) with water as solvent to obtain an enriched dry extract with specific polyphenols such as caffeine to dry or liquid state (pg. 4, [0031], [0033], [0034] and [0036]) and recombined with beverages and food suitable for human consumption (pg. 4, [0032]) as discussed above in claims 1 and 10. Miljkovic et al. discusses the detoxication process including air drying and sun drying coffee cherry to reduce the risk exposure of mycotoxin ochratoxin A and aflatoxins to be fit for human consumption (pg. 4, [0038]-[0042]).
- 16. Miljkovic et al. is silent on the sub-ripe stage of coffee cherry as cited in claim 2 and 15 and quick-drying the coffee cherry as cited in claim 3 and 16.

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17. However, Bucheli et al. discloses nonripe coffee cherry (sub-ripe coffee cherry) dried before being dehulled and separated into a green coffee and husk fractions (pg. 1359, col. 2, lines 15-23). Bucheli et al. discusses green coffee bean are well known in the art to be further processed into coffee soluble for beverage food product (pg. 1358, col. 1 lines 9-15). Bucheli's nonripe coffee cherry is not ripe and is considered to encompass an array of natural colors between red, yellow and green color mixture.

- 18. Bucheli et al. discloses measurement ochratoxins level (OTA) contains only trace amounts of OTA in green bean of coffee cherry in a range of not detectable up to 0.6 µg/kg (ppm) and coffee cherry husk fraction from about 0.2 to 0.9 µg/kg (ppm) (pg. 1359, col. 2, lines 19-23; pg. 1360, Table 1) during sun-drying (quick drying) within time period between zero day and under 5 days mark. Bucheli et al. teaches the maturity level in unripe cherries have no evidence for generation of OTA under any of the four drying conditions tested (pg. 1361, Table 4; col. 2, lines 6-8) and further discuss the overripe cherries are more prone to OTA contamination due to the sugar availability to affect microbial growth and molds (pg. 1361, col. 2, lines 11-14).
- 19. Bucheli clearly teaches that lower mycotoxins (ochratoxins) result from harvesting coffee cherries when they are under ripe (sub ripe) and also teaches drying of coffee cherries. It would have been obvious to one of ordinary skill in the art to use Bucheli's nonripe (sub-ripe) quick-dried coffee cherry in Miljkovic's extraction of ground (comminuted) whole coffee cherry because it would be beneficial to reduce the formation of high mycotoxins levels in food product and beverages for the health of humans and animals upon consumption.

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20. Bucheli et al. is silent on the mycotoxin levels of aflatoxins and fumonisins, However, Bucheli et al. clearly teaches the reduction of ochratoxin levels in coffee cherry material can be achieved by properly handling and drying whole coffee cherry. Furthermore, Bucheli et al. teaches selecting maturity stages of unripe coffee cherry are more optimal to have low mycotoxin levels compared to overripe coffee cherry and under optimal conditions within a short period of time after harvesting. Bucheli's dried coffee cherry is expected to have naturally low mycotoxin levels of aflatoxins and fumonisins. As Bucheli's coffee cherries are picked when they are subripe and are treated in a manner similar to that of the instant disclosure, it is expected that the levels of mycotoxins, specifically aflatoxins and fumonisins are commensurate with that of the claims, and as the ochratoxins have been shown to be within the ranges claimed.

- 21. Regarding claim 11, it is well known in the art of food ingredient processing to subject liquid ingredient to freezing drying step. It would have been obvious to freeze dry Miljkovic's extract to preserve and extend the shelf-life of the extract.
- 22. Regarding claims 18-20, it would have been obvious to market a food product with the information about the ingredients printed on at least on one of a container containing the formulation and a package containing the container. It would have been well within the purview of one ordinary skill in the art at the time of the invention was made to market the product to consumers. Additionally, it is well known to advertise ingredients on the packaging thereof. It is also well known that any benefits attributed to the food product are also indicated on the packaging thereof for the purpose of informing the consumer.

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23. Claims 1-3, 5, 8-11, 15, 16-19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boniello et al. (US 4,867,992) in view of Bucheli et al. (J. Agric. Food Chem. 48, 1358-1362).

- 24. Boniello et al. discloses a process comprising "comminuted" part of or all of the all-coffee nutrient media including soluble solids from green extract (aqueous green coffee solids), ground green coffee beans, coffee by products (pulp, coffee husks and mucilage), as well as hydrolyzed spent grounds, roast and ground coffee (col. 2, lines 57-63) with water. Examiner notes the ground green coffee beans, comminuted pulp, coffee husks and mucilage are part of whole coffee cherry fruit. Boniello et al. teaches employing ground green coffee beans (bean or seed) and coffee by products (pulp, coffee husks and mucilage) which is considered to be providing comminuted coffee cherry which was processed from a whole coffee cherry.
- 25. Boniello discloses nutria media comprising suitable coffee substances, including coffee by products which are (pulp, coffee husks and mucilage) and ground green coffee beans (col. 2, lines 57-63) to produce a natural flavor extract (col. 7, claim 1) then spray-dry or freeze-dry producing a combination to produce a soluble coffee solid food product (col. 8, claim 13) for human consumption (col. 4, lines 62-68). It is well known in the art to add liquid to soluble coffee to obtain a beverage.
- 26. Boniello is silent on the polyphenols-enriched coffee cherry extract.
- 27. However, Bucheli et al. discloses nonripe coffee cherries as discussed above.
 Bucheli et al. teaches an overlapping range of ochratoxins. Bucheli also teaches that the cherries are harvested when they are non-ripe which is considered sub-ripe. The

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level of polyphenols is inherent to the ripeness stage, with the levels decreasing as ripeness increases. Based upon this, the cherries of Bucheli will have a higher level of polyphenols than ripe cherries and are considered "enriched".

- 28. It would have been obvious to one of ordinary skill in the art to use Bucheli's unripe quick-dry coffee cherry with low mycotoxin levels of ochratoxin in Boniello's extraction of natural coffee flavors because Bucheli teaches the benefits of handling unripe (sub-ripe) coffee cherry to reduce formation of mycotoxins in food products. Bucheli clearly teaches that lower mycotoxins (ochratoxins) result form harvesting coffee cherries when they are under ripe (sub ripe) and also teaches drying of coffee cherries.
- 29. Bucheli et al. is silent on the mycotoxin levels of aflatoxins and fumonisins, However, Bucheli et al. clearly teaches the reduction of ochratoxin levels in coffee cherry material can be achieved by properly handling and drying whole coffee cherry. Furthermore, Bucheli et al. teaches selecting maturity stages of unripe coffee cherry are more optimal to have low mycotoxin levels compared to overripe coffee cherry and under optimal conditions within a short period of time after harvesting. Bucheli's dried coffee cherry is expected to have naturally low mycotoxin levels of aflatoxins and fumonisins. As Bucheli's coffee cherries are picked when they are subripe and are treated in a manner similar to that of the instant disclosure, it is expected that the levels of mycotoxins, specifically aflatoxins and fumonisins are commensurate with that of the claims, and as the ochratoxins have been shown to be within the ranges claimed.

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30. Regarding claims 18-20, it would have been obvious to market a food product with the information about the ingredients printed on at least on one of a container containing the formulation and a package containing the container. It would have been well within the purview of one ordinary skill in the art at the time of the invention was made to market the product to consumers. Additionally, it is well known to advertise ingredients on the packaging thereof. It is also well known that any benefits attributed to the food product are also indicated on the packaging thereof for the purpose of informing the consumer.

- 31. Claims 6, 7, and 11-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boniello et al. (US 4,867,992) and Bucheli et al. (J. Agric. Food Chem. 48, 1358-1362) as applied to claim 1 and 10 above, and further in view of Drunen (US 6.572.915 B1).
- 32. Boniello et al. and Bucheli et al. disclose the claimed invention as discussed in claim 1 and 10. Boniello does not teach an extraction with solvent and least partially evaporating the solvent.
- 33. However, Drunen et al. disclose a process of the selective extraction of antioxidants including caffeine, polyphenol and polysaccharides from comminuted coffee cherry husks to be returned back into food products such as drink or natural supplements (col. 1, lines 53-55; col. 3, lines 60-62, col. 4, lines 17-19). It would have been obvious to one of ordinary skill in the art to use Drunen's extraction in Boniello's process. Drunen clearly teaches successful extraction from coffee cherry husk byproducts of coffee cherry therefore Drunen's extraction process would expected to be to

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successful on Boniello's comminuted whole coffee cherry to obtain selective antioxidants including colvohenols.

- Regarding claim 6 and 7, Drunen discloses aqueous solvent (col. 3, lines 10-13) and evaporating the solvent (col. 5, Example V, lines 8-17).
- Regarding claim 11, Boniello discloses a process of freeze drying the extract (claim 31, col. 10, lines 11-15).
- 36. With respect to claims 12-14, Drunen et al. teaches chromatography with selective extraction for nutrients such as caffeine, polyphenol and polysaccharides (col. 3, lines 40-56). It would have been obvious to use any known method of for measuring the extract.

Response to Arguments

- 37. Applicant's arguments with respect to claims 1-3, and 5-20 have been considered but are moot in view of the new ground(s) of rejection.
- 38. Applicant argues Boniello does not teach the step of comminuting coffee cherry and is silent on the specific combination of coffee cherry components. Applicant argues Boniello does not discloses isolate a nutrient, fails to make any reference to any coffee cherry, and does not teach comminuted coffee cherry and does not make an extract but fermentation medium.
- 39. Bonillo teaches a comminuted coffee cherry comprising part (comminuted) of or all of the soluble solids from green extract (aqueous green coffee solids), ground green coffee beans, coffee by products (pulp, coffee husks and mucilage), as well as hydrolyzed spent grounds, roast and ground coffee (col. 2, lines 57-63). Examiner

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notes the comminuted pulp, coffee husks and mucilage are part of whole coffee cherry fruit. Boniello et al. teaches employing ground green coffee beans (bean or seed) and coffee by products (pulp, coffee husks and mucilage) which are considered to be providing comminuted coffee cherry which was processed from a whole coffee cherry. Boniello's comminuted whole coffee cherry comprising ground green coffee beans (bean or seed) and coffee by products (pulp, coffee husks and mucilage) are commensurate with the scope of the claims. Additionally, Boniello discloses both fermentation and extraction processes (col. 6, lines 1-11) to produce extracts diacetyl to be added to instant coffee soluble.

- 40. Applicant argues Drunen discloses the extraction process from coffee cherry by-product husks and not whole coffee cherry. Drunen clearly teaches successful extraction from coffee cherry husk by-products of coffee cherries therefore Drunen's extraction process would expected to be to successful on Boniello's comminuted whole coffee cherry to obtain selective antioxidants including polyphenols. Boniello's and Drunen's extraction process are both related techniques by extracting comminuted coffee cherries to obtain a desired extract to be recombined with a coffee food product.
- 41. Applicant refers to Miljkovic as showing the mycotoxin problem is associated with the pulp and parchment. However, Bucheli et al. clearly teaches as discussed above that with proper handling and drying practices the measurement ochratoxins level (OTA) contains only trace amounts of OTA in husk fractions of dried coffee cherries as well as the remaining parts of the cherries when subjected to sun-drying and between the zero day and under 5 days mark drying period. Bucheli et al. teaches that for maturity levels

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of the unripe cherries there is no evidence for generation of OTA under any of the four drying conditions tested (pg. 1361, Table 4; col. 2, lines 6-8) and further discusses that the overripe cherries are more prone to OTA contamination due to the sugar availability to affect microbial growth and molds (pg. 1361, col. 2, lines 11-14).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HONG MEHTA whose telephone number is (571)270-7093. The examiner can normally be reached on Monday thru Thursday, from 7:30 am to 4:30 pm EST..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jennifer McNeil can be reached on 571-272-1540. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Htm

/Jennifer C. McNeil/ Supervisory Patent Examiner, Art Unit 1784